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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,980	05/31/2005	Luigi De Ambrosi	SER-102.1P US	2926

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,980	DE AMBROSI ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 12/08/2006 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-10 have been canceled.

2. Claim 11 has been amended.

3. Remarks drawn to objections to Specification and rejections under double patenting and 35 USC 102 and 103.

Claims 11-16 are pending in the case.

Specification

The objection to the Specification has been overcome by amendment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of Claims 1, 3 and 7 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 5 of U.S. Patent No. 7,091,337 ('337 patent) has been rendered moot by the cancellation of instant claims 1, 3 and 7.

The following rejection is necessitated by amendment.

Instant claim 1 is drawn to a process for depolymerizing glycosaminoglycans comprising exposing the glycosaminoglycan to electron-beam radiation. Claim 1 of the '337 patent is also drawn to the same process using a high-energy radiation.

Claims 11, 13 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 5 of U.S. Patent No. 7,091,337 ('337 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 11 is drawn to a process for depolymerizing glycosaminoglycans comprising exposing an aqueous solution glycosaminoglycan to electron-beam radiation, optionally in the presence of 0.1% to 5% of an organic compound. Claims 1 and 5 of the '337 patent are also drawn to the same process using a high-energy radiation, in the presence of 0.1% to 5% of an organic compound.

Instant claims 13 and 15 recite limitations wherein heparin is the glycosaminoglycan and specific organic compounds in the presence of which the process is carried out. Claims 2 and 4 of the '337 patent also recite the same limitations.

It would have been obvious to one of ordinary skill in the art that instant claims 11, 13 and 15 are substantially overlapping with claims 1, 2, 4 and 5 of the '337 patent. One of ordinary

skill in the art would be motivated to perform the process as instantly claimed since the starting material and solvents are the same and the process would be expected to depolymerize the glycosaminoglycan when irradiated with high-energy radiation like electron beam.

Instant claims 11, 13 and 15 must recite limitations that are patentably distinct from those of claims 1, 2, 4 and 5 of the '337 patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1, 3 and 5 under 35 U.S.C. 102(b) as being anticipated by Cho et al (KR 20000036332, English Abstract) and the rejection of Claim 10 under 35 U.S.C. 102(b) as being anticipated by De Ambrosi et al (US 4,987,222) have been rendered moot by cancellation of the claims.

The following rejection is necessitated by amendment.

Claims 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho et al (KR 20000036332, English Abstract) of record.

Cho et al teach preparation of low molecular weight heparin by exposing an aqueous solution of high molecular weight heparin using electron beam. This is seen to meet the limitations of instant claims 11 and 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of Claims 2, 4 and 9 under 35 U.S.C. 103(a) as being unpatentable over Cho et al (KR 20000036332, English Abstract) has been rendered moot by cancellation of the claims. The following rejection is necessitated by amendment.

Claims 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al (KR 20000036332, English Abstract) of record.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 12 is drawn to a process of depolymerization of a glycosaminoglycan by exposing it to electron beam, wherein the process involves dynamic irradiation. Claims 14 and 16 recite limitations drawn to energy and dosage of the radiation.

Cho et al teach preparation of low molecular weight heparin by exposing an aqueous solution of high molecular weight heparin via to an electron beam. Even though Cho does not specifically state that his process involves dynamic irradiation, the specific dosage or energy of the radiation it would have been obvious to perform the process wherein the solution containing the glycosaminoglycan is fluxing as a thin stream in front of the electron beam source. It is well within the purview of one of ordinary skill in the art to adjust the dosage and the energy of the radiation used for the purpose of optimization.

One of ordinary skill in the art would be motivated to perform the process using dynamic irradiation as instantly claimed since such a process, which is similar to a continuous process, would allow for preparation of large amounts depolymerized heparin ins a shorter time period.

Response to Applicants Remarks

Applicants have added new claim 11 incorporating the limitations of original claims 5, 6 and 8 into original claim 1 and have amended new claim 11 in a supplemental amendment by substituting the term "comprising' with the term "consisting". Applicants have also argued that the amended claims avoid the critical photocatalyst required by the Cho reference.

Applicants' argument is not found to be persuasive.

The rejections are still being maintained. Cho's reference uses a photocatalyst to produce the depolymerized glycosaminoglycan. The final product is not seen to be different from the product obtained in the instant case. The presence of the photocatalyst is not seen to make a difference. Moreover, the presence of the organic compound is optional. Cho's reference is still seen to read on the instant invention. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Conclusion

Claims 11-16 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

3/1/07

Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623